



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: NIKOLAI. AFANASENKO ET AL. (PCT)

SERIAL NO.: 08/646,213

GROUP: 3302

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EXAMINER: J. CLARK

TITLE: DEVICE FOR TREATMENT OF PATIENTS WITH DISTURBED POSTURE
AND MOTOR ACTIVITY

DECLARATION UNDER RULE 132

ATTN: BOX FEE AMENDMENT
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, GALINA IVANOVNA BELOVA, declare that since 1978, I have been Medical Superintendent of the "Kaluga-bor" Republican Children's Psychoneurological Sanatorium, Honored Physician of the Russian Federation; and

I, TIMOFEI GRIGORIEVICH SHAMARIN, declare that since 1989, I have been Deputy Medical Superintendent, Cand. Sc. (Med.), Highest Degree neuropathologist; and

that the following clinical tests (EXHIBIT E) were conducted under our supervision:

EXHIBIT E

REPORT

on clinical trials of the JK-92 "Adeli"
therapeutic suit at the "Kaluga-bor"
Republican Children's Psychoneurological
Sanatorium, Russian Federation,
performed from July 25 to August 25, 1994

Over twenty thousand child patients suffering from infantile cerebral paralysis and cerebral paralyzes of various etiologies have been treated for a 25-year period at the "Kaluga-bor" Republican Sanatorium. 15 percent of the patients could not walk spontaneously. After a three- or four-month treatment period 70 percent of a total number of non-walking patients could walk unassistedly or using an additional support, while the other 30 percent of patients often remained non-walking even after repeated treatment courses.

Many years of practical experience at the sanatorium demonstrated that a generally adopted therapy proved to be ineffective in some patients who exhibited hyperkinetic forms of infantile cerebral paralysis.

In view of the foregoing, a group of child patients (10 persons)

was selected, in whom the conventional therapy failed to give the desired positive results.

Presented below are characteristic data of the patients under treatment and variation in the principal locomotor and other functions in the course of treatment with the aid of the "Adeli" therapeutic suit.

1. Male patient Visternichan Radu, 15, from Moldova, case history No.37. Diagnosis: secondary conditions to sustained neuroinfection accompanied by severe tetraparesis. Cerebellar and cerebrosthenic syndromes. Cerebellar dysarthria. I or II-degree episynndrome.

The patient had been permanently treated at the various specialized medical institutions, including repeated treatment courses given at the "Kaluga-bor" sanatorium.

Objective evidence: the patient can stand and walk with crutches and his mother's help, which requires vast physical efforts on her part. While walking with crutches and mother's assistance the patient exhibits his legs semiflexed in the knee and hip joints and do not virtually separate from the bearing surface. There was noted conspicuously pronounced weakness of all groups of muscles,

acrocyanosis and hyperhidrosis of the palmar and plantar surfaces of hands and feet, respectively.

The patient was given treatment with the "Adeli" therapeutic suit by 30-minute sessions for 15 days. On the second day of treatment the patient refused his mother's help in walking and started walking with crutches alone. By the end of the treatment course the patient could walk relatively stably without his mother's assistance and only with crutches. He could also go upstairs and downstairs without his mother's help. While walking the patient could separate his legs well from the bearing surface and raise them for an adequate height. In the course of treatment the patient's body weight was reduced by 6 kg at the expense of the subcutaneous fat, and acrocyanosis and hyperhidrosis decreased considerably.

2. Female patient Pozhidaeva Julia, 12, from the city of Tula, Russian Federation, case history N 550. Diagnosis: infantile cerebral paralysis. Severe spastic diplegia. Slight dysarthria. Cerebrosthenic syndrome.

The patient was treated in various medical institutions, including those in the city of Tula, with the aid of incisors.

Objective evidence: the patient can neither stand nor walk spontaneously and cannot be taught walking with the aid of an additional support (crutches) . When assisted by her mother the patient can make a few steps; while walking the patient's head and trunk are bent forward, and the legs are rotated inwards at the hip joints. The patient was given treatment with the aid of the "Adeli" therapeutic suit for 20 days. After the initial four treatment sessions the patient could walk with crutches. By the end of the treatment course the patient could walk with crutches unassistedly in a relatively correct posture. Her motivation and striving to improve her capabilities increased considerably.

Eight other patients whose brief case histories are not present in the this Report, have suffered from spastic diplegia and hyperkinetic form of infantile cerebral paralysis. All of them exhibited significant positive treatment results, namely, their statics and locomotion are improved, hyperkinesis events become less frequent and of lower intensity, and motivation is increased.

Conclusions:

1. No negative effects are found to result from treatment courses

with the aid of the "Adeli" therapeutic suit.

2. Positive results are attained, using the "Adeli" therapeutic suit in situations where the conventional generally adopted rehabilitation therapy proves to be ineffective.

In addition, treatment with the "Adeli" therapeutic suit produced a positive therapeutic effect in patients with vegetative dysfunctions, endocrinopathies, and metabolic disorders.

Each of us hereby declares that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any

patent issued thereon.

Date: 21.07.98.

Белова
Name: G.I. Belova

Title: Medical Superintendent of the "Kaluga-bor"
Republican Psychoneurological Children's Sanatorium,
Honored Physician of the Russian Federation

Date: _____

21.07.98. Шамарин
Name: T .G. Shamarin

Title: Deputy Medical Superintendent, Cand.Sc. (Med),
Highest Degree neuropathologist